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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,554	01/18/2001	Juan Carlos Parodi	BSI-320US1	1961

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

16

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/764,554

Applicant(s)

PARODI, JUAN CARLOS

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2003 and 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments filed November 24, 2003 have been fully considered but they are not persuasive. The applicant has argued that Kugler does not disclose a reference to an actual shape for the transition. Although the shape of the transition is not explicitly disclosed, it is shown in the drawings to flare outward and is interpreted by the examiner to be concave and trumpet shaped. Applicant has argued that Kugler's transition is more conical than concave looking. Conical and concave are both outwardly flaring and what distinguishes one over the other, is where the branch end it placed in the lumen. Specifically, how much the branch lumen is stretched when anchored. The same flare will appear conical if stretched and pulled taut upon anchoring, and will appear concave, trumpet shaped if left loose and anchored at a more proximal position within the lumen. Either way, the flare on the prosthesis is the same before implantation, therefore the same end product. Applicant has also argued for the first time, that there is an advantage of having a concave trumpet shape transition over a conical transition and that is that the concave transition may be made over a shorter length (although, as discussed above, the conical transition will be concave trumpet shaped if anchored more proximally, over a **shorter length** as applicant has noted). There is no reference in the specification that there is an advantage of one over the other. In fact, the specification seems to point out that any flare shape, conical, concave trumpet shape, or otherwise, is sufficient for retaining the distal end in a lumen, page 9 recites, "As it is shown in Fig. 4, a first embodiment shows that the transition or merging between a limb 13 and its distal end portion 15 may be devised through a curved trumpet-shaped transition portion 17. Fig. 5 shows another embodiment where the transition portion is a conical

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portion 18. In any case, distal end portion 15, 16 may be cylindrical or **may have any shape provided that the end portion is sized and configured to be efficiently retained into the corresponding iliac artery**, as shown in Fig. 3.” Applicant has also argued that Strecker actually teaches away from the invention by disclosing a prosthesis that is unbranched and designed to be kept out of branch lumen. The examiner disagrees. Whether Strecker’s prosthesis is branched or unbranched is irrelevant, Strecker still discloses an endoluminal prosthesis. Strecker was used as a teaching for flaring ends of endoluminal prostheses in a trumpet shape in order for better anchorage of the prosthesis, to prevent slippage. Where the prosthesis is placed proximal or distal of the branch is irrelevant, the important thing is that Strecker is using trumpet shaped flare on the ends of endoluminal prosthesis for better anchorage, preventing slippage. This will prevent slippage and anchor well, whether placed proximal or distal of the branch in the lumen. The rejections still stand.

***Claim Rejections - 35 USC § 101***

Claims 7, 13, and 16 are directed toward non-statutory subject matter. The claims positively recite portions of the body, which is non-statutory subject matter and should be corrected. Claim 7, line 10 recites, "diameters is less than the restricted section inner diameter", claiming the size of the restricted lumen. Claim 13, lines 9-10 and lines 12-13 recite, "diameter which is less than one-half of the restricted diameter" and "greater than one-half of the restricted diameter" respectively, claiming the size of the restricted lumen again. Claim 16, line 3 recites, "diameters 20% greater than the restricted diameter", claiming the size of the restricted lumen again.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-16 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kugler et al. (USPN 6,129,756, cited in previous office action). Kugler discloses an endoluminal device and method of treating a lumen (col.2, lines 30-45) substantially as claimed. See figure 2 and respective portions of the specification. Kugler discloses a proximal main tubular portion (10) having a first diameter, two tubular limbs (20), (30), having a second diameter, wherein the distal ends of the limbs (near (22) and (32)) have a

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third diameter that is cylindrical and larger than the second diameter (col.5, lines 25-31; col.9, lines 8-17; col.10, lines 26-42). Kugler has shown in Fig.2, a flared transition from the second diameter to the third diameter (col.9, lines 8-17). Because the point of inflection will not be an exact 90°, or sharp angle, the flared transition is inherently curved, thus concave and trumpet shaped.

In the alternative, Kugler has shown in Fig.2, a flared transition from the second diameter to the third diameter (col.9, lines 8-17) that appears the same as the transition portion shown by the applicant in figure 5. Since the applicant teaches use of flared transitional portions of endoluminal devices for the purpose of anchoring, flared being either conical (fig.5) or concave trumpet-shaped (fig.4) and the applicant has not disclosed an advantage for a concave flare verses a conical flare, it would have been an obvious matter of design choice to have a concave transitional portion, which would perform equally as well as the conical transitional portion.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (USPN 5,575,817, cited in applicant's IDS) in view of Strecker (USPN 5,405,378). Martin discloses an endoluminal device and method for treating a lumen (col.1, lines 35-41; col.4, 1-35) substantially as claimed. See figures 1, 4 and respective portions of the

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specification. Martin discloses a proximal main tubular portion (6) having a first diameter, two tubular limbs (4), (2), having a second diameter, wherein the distal ends of the limbs have a third diameter larger than the second diameter (area near (12)). Martin has shown in fig.1 and 4 a transition portion from a tubular limb to a distal end having an increase in diameter, however does not specify the transitional portion to be concave or trumpet shaped. Strecker teaches in the same field of endoluminal devices, the use of trumpet-shaped ends on device used near branch vessels, for the purpose of preventing slippage near the branch, thus anchoring the device in place (col.6, lines 1-9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Martin's endoluminal device with Strecker's teaching of trumpet-shaped ends on endoluminal device's in order to prevent slippage of the device near the branch vessel, thus anchor the device in place.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Cheryl Miller**



**BRUCE SNOW  
PRIMARY EXAMINER**